NO. 23-55742

IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, ET AL.,

Plaintiffs-Appellees,

TAKEDA PHARMACEUTICAL COMPANY, LTD., ET AL.,

Defendants-Appellants.

On Appeal from the United States District Court for the Central District of California (Case No. 2:17-cv-7223) (Hon. John W. Holcomb)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING APPELLANTS AND REVERSAL

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DISCLOSURE STATEMENT

Washington Legal Foundation has no parent company, issues no stock, and no publicly held company owns a ten percent or greater interest in it.

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INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. WLF often appears as an amicus curiae in important class actions to combat attempts to abuse Rule 23 and the class mechanism. *See, e.g.*, *TransUnion LLC v. Ramirez*, 594 U.S. 413 (2021); *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338 (2011).

WLF's Legal Studies division, the publishing arm of WLF, regularly produces articles by outside experts on class certification. *See, e.g.*, Frank Cruz-Alvarez & Britta Stamps, *Individualized Assessments of Employees Stopped a Class Action in Its Tracks*, WLF Legal Opinion Letter (June 4, 2020), https://perma.cc/J4SA-THJZ; Lindsay Breedlove, *Meticulous Predominance Assessment Sinks Pharma-Marketing RICO Class Action*, WLF Legal Backgrounder (Aug. 12, 2016), https://perma.cc/7CQZ-XHBU.

WLF has long opposed efforts to transform the class action from a procedural device aimed at avoiding the inefficiencies of deciding the same

* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties consented to the filing of this brief.

claims repeatedly into a tool for altering the parties' substantive rights. WLF fears that the district court's dilution of Rule 23's venerable protections, if allowed to stand, would have disastrous consequences for litigants and the courts.

INTRODUCTION & SUMMARY OF ARGUMENT

So much class litigation ignores the basic reality that some claims simply aren't amenable to class treatment. This case proves the point. A class action is "an exception to the usual rule that litigation is conducted by and on behalf of individual named parties only." *Dukes*, 564 U.S. at 348 (cleaned up). Rule 23 thus "imposes stringent requirements for certification that in practice exclude most claims." *Am. Express Co. v. Italian Colors Rest.*, 570 U.S. 228, 234 (2013). That is no tragedy. On the contrary, it is a virtue of our legal system's commitment to due process and the rule of law.

Class certification is often "the whole shooting match." David L. Wallace, *A Litigator's Guide to the 'Siren Song' of 'Consumer Law' Class Actions*, LJN's Prod. Liab. L. & Strategy 10 (Feb. 2009); *see Blair v. Equifax Check Servs., Inc.*, 181 F.3d 832, 834 (7th Cir. 1999). "With vanishingly rare exception, class certification sets the litigation on a path

toward resolution by way of settlement, not full-fledged testing of the plaintiffs' case by trial." Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. Rev. 97, 99 (2009). As the Supreme Court has recognized, "extensive discovery and the potential for uncertainty and disruption in a lawsuit allow plaintiffs with weak claims to extort settlements from innocent companies." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 163 (2008) (citing *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 740-41 (1975)).

There is thus an "inherent tension" between "representative suits" and our "deep-rooted historic tradition that everyone should have his own day in court." *Ortiz v. Fireboard Corp.*, 527 U.S. 815, 846 (1999). When that tension runs too high, as in this case, it is the *privilege* of bringing a class action that must give way and the *right* to a fair legal process that must stand firm. A plaintiff may combine only those claims truly "capable of class-wide resolution"—claims that can be resolved "in one stroke." *Dukes*, 564 U.S. at 350. Contrary to the district court's certification order, Plaintiffs' claims do not allow for one-stroke resolution here.

Plaintiffs allege that two pharmaceutical manufacturers, Takeda and Eli Lilly, induced diabetes patients and third-party payors (TPPs) to

pay for a greater number of prescriptions for the popular diabetes drug Actos than they would have had they known of an allegedly elevated risk of bladder cancer in some patients. As Plaintiffs see it, if that alleged risk had been properly disclosed, some doctors would have written fewer Actos prescriptions, leading some patients and TPPs to spend less money on Actos. But the parties agree that even *with* the disclosure, many patients' physicians would have continued to prescribe Actos. Thus, Plaintiffs' key evidentiary problem is how to distinguish those Actos prescriptions that *would have been* written despite such disclosure from those that *would not have been* written because of that disclosure. And as the district court itself recognized, making that distinction entails an individualized inquiry into the medical factors relevant to each patient's therapy and unique medical history.

As the district court also recognized, the need for individualized "physician-patient" inquiries makes the certification of a class of Actos patients impracticable. (1-ER-37) Yet the court nevertheless certified a sweeping class comprising *every TPP in the country* that paid for at least five "independent" Actos prescriptions between 1999 and 2010. That

decision rested on two manifest errors, among many others, that contravene Rule 23 and invite reversal.

The first error was the district court's erroneous conclusion that the key question here—which Actos prescriptions would *not have been* filled if the alleged side effect had been more fully disclosed?—may be answered mainly through common evidence, at least in resolving the TPP claims. But the TPP claims rise and fall with the individual patients' claims. As the district court correctly recognized, those individual patients' claims will be resolved largely through individualized evidence. So will the TPP claims.

The second error was the district court's bizarre suggestion that whether individualized questions will predominate over common ones comes down to the "tally" or "quantum" of individualized evidence in the record *at the class-certification stage*. (1-ER-31, 1-ER-38 n.146) That approach, which demands that the parties put on all their individualized evidence up front at the class-certification stage, finds no footing in Rule 23. Indeed, the whole point of the class-certification inquiry in Rule 23(b)(3) cases is to scrutinize whether class adjudication will entail the costly preparation of individualized proof. Demanding a cumbersome

presentation of that same proof before a class has even been certified is self-defeating.

The district court's clear misapplication of Rule 23 in this $7 billion case merits reversal.

ARGUMENT

I. RESOLVING PLAINTIFFS' CLAIMS REQUIRES INDIVIDUALIZED PROOF THAT PRECLUDES CLASS CERTIFICATION.

Class actions are an "exception to the usual rule" of individualized adjudication. *Califano v. Yamasaki*, 442 U.S. 682, 700 (1979). They are "peculiarly appropriate" when the "issues involved [in the case] are common to the class as a whole," and it is "unlikely that differences in the factual background of each claim will affect the outcome of the legal issue." *Id.* at 701. In those cases, "the class-action device saves the resources of both the courts and the parties by permitting an issue potentially affecting every [class member] to be litigated in an economical fashion." *Id.* Thus, Rule 23(b)(3) calls for class adjudication only where the "questions of law or fact common to class members predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). For only in those cases will class adjudication of individual damages claims prove "convenient." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 615 (1997) (quoting Fed. R.

Civ. P. 23 advisory committee's notes to 1966 Amendment). As the Supreme Court has emphasized, class adjudication makes sense only when a court will be able to resolve the issues "central to the validity of each one of the [individual] claims in one stroke." *Dukes*, 564 U.S. at 350.

Consider a securities case premised on a "fraud-on-the-market" theory of liability. *See, e.g.*, *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804 (2011). Such a theory rests on the legal presumption that a public, material misrepresentation about a security will be reflected in the security's price, and that *any* investor who trades in the market will rely on the security's price as an unbiased assessment of that security's value. *Id.* at 811. Without that presumption—which has no application here—securities class litigation would be impossible, "since individual issues" of reliance would "overwhelm[ ] the common" issues in the case. *Id.* at 810 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 242 (1988)). The presumption allows the issue of reliance to be litigated on a class-wide basis, making it possible to resolve class members' claims in a single stroke. *Id.*

That is not true here, where no class-wide presumption like the fraud-on-the-market theory applies. *Cf. Bridge v. Phoenix Bond & Indem,*

Co., 553 U.S. 639, 658 (2008) (noting that a RICO plaintiff will ordinarily "not be able to establish even but-for causation" without showing "that *someone* relied" on alleged misrepresentations or omissions). As the district court recognized, the claims here turn on a question about what physicians who prescribed Actos (and the patients who took it) *would have done* if Actos's label had warned of alleged bladder-cancer risks. (1-ER-37) The district court held that there can be no presumption that physicians would have stopped prescribing Actos in the face of such a warning; indeed, Plaintiffs' own expert concluded that over 40% of Actos purchases would have been made even if Actos had carried that warning. (1-ER-39, 1-ER-41) The district court also recognized that the inquiry into *which* patients would have dropped Actos because of the alleged failure to disclose is "highly individualized" because, among other reasons, some alternative "medicines and treatment regimens would be ineffective" and "some patients would have no . . . option other than Actos, notwithstanding the bladder cancer risks." (1-ER-37) That inquiry "necessarily reside[s] with the [individual] patients and their physicians." (*Id.*) Thus, the district court correctly concluded that a class of Actos

patients was impossible because "individualized questions of fact [would] predominate" in any litigation. (1-ER-39)

Yet the district court certified a nationwide class of *TPPs* that reimbursed at least five of those individual patients' prescriptions. In support of that result, the district court determined that expert analysis—combined with "direct evidence of internal company emails, marketing studies, and other testimony" (1-ER-26)—might establish that some patients would have switched away from Actos (and thus that some TPPs paid for excess Actos prescriptions) to establish through common evidence "but-for causation . . . for a single TPP or even for a class of them." (1-ER-28) Even so, the district court called it "an open question whether a class of TPPs may successfully leverage common evidence of the kind offered here . . . without running into the need for individualized analysis—or, at least, without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones." (*Id.*) And it also recognized that "Takeda or Lilly could . . . depose individual prescribing physicians to contest Plaintiffs' theory of but-for causation," and that "such evidence would constitute individualized evidence" leading

to "individualized factual determinations [that] would swamp common ones." (1-ER-29)

The district court's reasoning is at war with itself. The district court, having recognized that individual patients' claims would require individualized "physician-patient" inquiries (1-ER-37), and having conceded that the same inquiries were likely to loom large in any claims brought by the TPPs (1-ER-29), should have concluded that such claims cannot be adjudicated on a class-wide basis. The purpose of class actions is to enable the "convenient" adjudication of multiple claims simultaneously, *Amchem Prods.*, 521 U.S. at 615 (citation omitted), and there is nothing convenient about deposing innumerable physicians to test the individual claims of thousands (or even hundreds of thousands) of TPPs en masse. Nor is it permissible to jettison such inquiries simply to achieve class certification. *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619, 625 (D.C. Cir. 2019); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 52 (1st Cir. 2018). Once the district court recognized the "real and significant risk" of such individualized adjudication, the decision to deny the class-certification motions should have been straightforward. (1-ER-29)

Indeed, the Second Circuit reached just that result on highly similar facts in *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) (*Zyprexa*). There, the Second Circuit correctly held that TPP class plaintiffs could not rest their overpayment claims on generalized proof "when individual physicians prescribing Zyprexa may have relied on Lilly's alleged misrepresentations to different degrees, or not at all . . . [and] when different TPPs may have paid for different 'excess' quantities of prescriptions." *Id.* at 136. Because—as the district court itself acknowledged—individualized evidence about the decisions of prescribing physicians threatens to dominate the adjudication of the claims here, those claims cannot be adjudicated on a class-wide basis. The district court's contrary decision was "manifestly erroneous," and should be reversed. *Chamberlan v. Ford Motor Co.*, 402 F.3d 952, 959 (9th Cir. 2005).

II. THE DISTRICT COURT'S CLASS-CERTIFICATION ANALYSIS FLOUTS RULE 23 AND THIS COURT'S PRECEDENT.

The district court not only reached the wrong conclusion; it did so through a class-certification analysis that is indefensible, and that—if affirmed on appeal—could generate significant, recurring problems for the class-certification process in other cases.

At class certification, the district court's core responsibility is to "com[e] to rest on the certification question" following "a rigorous analysis" of whether Rule 23's requirements are satisfied. *Dukes*, 564 U.S. at 350-51 (quoting *Gen. Tel. Co. of the Sw. v. Falcon*, 457 U.S. 147, 160-61 (1982)). Even if coming to rest in *favor* of class certification, a district court must find that the "party seeking class certification" has "affirmatively demonstrate[d] his compliance with the Rule." *Id.* at 350. Thus, where a party opposing class certification has credibly "summon[ed] the spectre of class-member-by-class-member adjudication," the district court "must determine" whether the party seeking certification has proven that "class-member-by-class-member assessment of the individualized issue will be unnecessary or workable." *Van v. LLR, Inc.*, 61 F.4th 1053, 1069 (9th Cir. 2023).

Here the district court never made that determination. Again, the district court expressly conceded the "real and significant risk [ ] that individualized factual determinations would swamp common ones" in this case. (1-ER-29) But it held that it was "premature" to investigate that risk because the extent of individualized evidence was "not clear" from the class-certification record. (1-ER-30) Instead, it simply waved away the

"spectre of class-member-by-class-member adjudication," *Van*, 61 F.4th at 1069, by classifying as "conjecture" and "speculat[ion]" any possibility that Takeda and Lilly would call individual physicians to make their case at trial. (1-ER-31) In the district court's view, that risk could safely be ignored because Takeda and Lilly had presented excerpts from only two individual prescribing physicians' depositions at the class-certification stage. *Id.* at 29. Thus, the district court assumed that "if the trial was held today," *only* those two physicians would be presented as witnesses, and "individualized issues would not predominate." *Id.*

That assumption was error. Indeed, it is the same error that caused this Court to reverse in *Van*. There, as here, the district court assumed that because the defendant had presented individualized evidence at the class-certification stage as to only a "de minim[i]s" number of class members, class certification was appropriate. *Van*, 61 F.4th at 1068. But as this Court recognized, that analysis rested on a basic "misunderstanding of the Rule 23 inquiry," since the defendant's invocation of even "a small number" of individualized proofs sufficed to show "that an inquiry into the [individualized] circumstances" of each class member "might be necessary." *Id.* at 1068-69.

Besides, *Plaintiffs* bear the burden of satisfying Rule 23's predominance and commonality requirements. *See Dukes*, 564 U.S. at 350. In meeting that burden, "actual, not presumed, conformance" with the rule is "indispensable." *Falcon*, 457 U.S. at 160. As the party seeking class certification, Plaintiffs "must affirmatively demonstrate [their] compliance with [Rule 23]—that is, [they] must be prepared to prove that there are in fact sufficiently numerous parties, common questions of law or fact, etc." *Dukes*, 564 U.S. at 350. Because Plaintiffs simply cannot meet that burden, the district court erred by certifying the class.

Adopting the district court's approach would defeat the whole point of the predominance inquiry at the class-certification stage—to weed out putative class actions that cannot be "efficiently" adjudicated on a class basis because "questions of law or fact common to class members" do not "predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). It cannot be that the only way of establishing that class adjudication would be inefficient is by wastefully submitting countless pieces of individualized evidence. Such an approach would only increase the delays and costs attendant to a form of proceeding that is supposed to facilitate the "convenient" litigation of multiple claims. *Amchem Prods.*,

521 U.S. at 615 (citation omitted). This Court should reverse to reaffirm the common-sense notion that a sampling of individualized evidence may suffice to show that individualized issues will predominate over common issues.

* * *

Where a case requiring a high degree of individualized adjudication is certified as a class action, it is not merely inconvenient. It threatens the rights of the parties and the absent class members, whose chance to fairly litigate each claim is severely diminished. That is especially so when, as here, the sheer size of a potential damages verdict (up to $7 billion) would force most defendants "to settle without relation to the merits of the class's claims." *Chamberlan*, 402 F.3d at 960 (quoting *In re Lorazepam & Clorazepate Antitrust Litig.*, 289 F.3d 98, 108 (D.C. Cir. 2002)).

CONCLUSION

This Court should reverse.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limits of Federal Rule of Appellate Procedure 29(a)(5) because it contains 2,889 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (6) because it uses 14-point Century Schoolbook font.

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